DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-558/S-038
NDA 19-778/S-030

Merck and Company, Inc.
Attention: Dr. Michael C. Elia
P. O. Box 4
Sumneytown Pike, BLA-20
West Point, PA 19486

Dear Dr. Elia:

Please refer to your supplemental new drug applications dated July 20, 1999 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prinivil (lisinopril) Tablets (NDA 19-558) and Prinzide (lisinopril/hydrochlorothiazide) Tablets (NDA 19-778).

We acknowledge receipt of your submissions dated September 14, 2000 and June 18, 2001. Your submissions of June 18, 2001 constituted a complete response to our August 25, 2000 action letter.

These supplemental new drug applications provide for final printed labeling containing class labeling text that states that non-steroidal anti-inflammatory drugs may diminish the antihypertensive effect of ACE inhibitors. In addition, text has been added for Prinzide under **DOSAGE AND ADMINISTRATION** that defines the upper dosing limit.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert included in your June 18, 2001 submission). Accordingly, these supplemental applications are approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Sandra Birdsong
Regulatory Project Manager
(301) 594-5334

Sincerely,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research